establishment where it was manufactured.

[39 FR 18939, May 30, 1974, as amended at 41 FR 48268, Nov. 2, 1976; 42 FR 15675, Mar. 22, 1977]

§ 433.17 Exemption for investigational use.

A shipment or other delivery of an antibiotic drug shall be exempt from section 502(l) of the act or the certification requirements of section 512(n) of the act if all the procedures outlined in part 312 or § 511.1 of this chapter are complied with. For the purposes of this section, the references in part 312 or § 511.1 of this chapter to ''new drug'' and ''approved new animal drug application'' shall be deemed to read ''antibiotic drug'' and ''approval for certification or exemption from certification'' respectively.

[39 FR 18939, May 30, 1974, as amended at 40 FR 13497, May 27, 1975; 55 FR 11582, Mar. 29, 1990]

Subpart C—Specific Use Exemptions

§ 433.20 Antibiotic drugs for isolation and differentiation of microorganisms in clinical use.

Antibiotic drugs subject to section 507 of the act shall be exempt from section 502(l) if such drugs are:

(a) Paper discs impregnated with antibiotics in the amounts listed in the following table:

Antibiotic	Content per disc
Bacitracin	0.04 unit.
Nystatin	100 units.

(b) Packaged in a container bearing on its label or labeling the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The potency of each disc in the batch.

(iii) The expiration date as prescribed under § 432.5(a)(3) of this chapter.

(iv) The statement: Not for Susceptibility Testing.

(2) On the labeling within or attached to the package: Adequate directions for use.

§ 433.21 Antibiotics for diagnostic use.

Antibiotics packaged for the withdrawal of individually weighed portions and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled shall be exempt from the certification requirements of section 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if they comply with all the following conditions:

(a) The potency, moisture content, and identity comply with the standards prescribed for the antibiotic by the specific regulations issued in this chapter.

(b) It is packaged in immediate containers that are tight containers as defined by the U.S.P. Each such container shall contain not more than 1 gram.

(c) Each package bears on the label or labeling of its outside wrapper or container and the immediate container the following:

(1) The statements ''For the withdrawal of individual portions of antibiotic. Each portion must be weighed before use. Diagnostic reagent. For professional use only.''

(2) The number of milligrams or grams contained in each immediate container and the potency per milligram.

(3) The batch mark.

(4) The statement ''Expiration date _____'', the blank being filled in with the date that does not exceed the expiration date authorized for the antibiotic by this chapter.

(d) The circular or other labeling within or attached to the package bears directions adequate for the use of such drug.

CROSS REFERENCES: For tests and methods of assay and certification of antibiotics susceptibility discs for laboratory diagnosis of disease, see §§ 460.1 and 460.6 of this chapter.

§ 433.22 Biologic drugs that contain antibiotics as a preservative.

Biological drugs that contain any certifiable antibiotic drug subject to the regulations in this chapter, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502(l) and 507 of the act and

the certification requirements of section 512(n) of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U.S.C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

§ 433.23 Microbiological culture media containing antibiotics.

Microbiological culture media that contain any certifiable antibiotic drug subject to the regulations in this chapter shall be exempt from the requirements of sections 502(l) and 507 of the act and the certification requirements of section 512(n) of the act if:

(a) They are intended for use in tissue culture and the antibiotic drug is added solely for use as an aid in the prevention of microbial contamination; or

(b) They are intended for use in the isolation of selected organisms from mixed cultures and the antibiotic drug is added solely for use as an aid in such isolation; and

(c) The certifiable antibiotic drug used in such culture media complies with the applicable standards of identity, strength, quality, and purity prescribed therefor.

§ 433.24 Exemption of antibiotic drugs for use in teaching, law enforcement, research, and analysis.

Antibiotic drugs subject to section 507 or 512(n) of the act shall be exempt from the requirements of section 502(l) and from the certification requirements of section 512(n) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or in law enforcement; or in research not involving clinical use; or in chemical analysis or physical testing, provided they are to be used only for such instruction, law enforcement, research, analysis, or testing, and provided further that their labels bear the statement ''Not for drug use.''

§ 433.25 [Reserved]

§ 433.26 Neomycin sulfate ointment intended for hypersensitivity testing.

Neomycin sulfate ointment subject to sections 502(l) and 507 of the act and packaged for use as an allergen for skin patch testing of hypersensitivity shall be exempt from the certification requirements of section 502(l) and 507 of the act if it complies with all the following conditions:

(a) It contains neomycin sulfate equivalent to 200 milligrams of neomycin per gram in petrolatum.

(b) The neomycin sulfate used in preparing the neomycin sulfate ointment conforms to the standards prescribed by § 444.42(a)(1) of this chapter except § 444.42(a)(1)(ii).

(c) The shipment of neomycin sulfate is made as a result of a specific request made to the manufacturer or distributor by a practitioner licensed by law to administer such drug, and the use of neomycin sulfate ointment for patch testing is not promoted by the manufacturer or distributor.

(d) Each package shall bear on its outside wrapper or container and on the immediate container, in addition to other labeling information required by the act and regulations, the following statements in lieu of adequate directions for use:

(1) The statement, ''Caution: Federal law prohibits dispensing without prescription''.

(2) The statement, ''For use only in patch testing''.

(3) The potency of the ointment.

(4) The expiration date as prescribed by § 432.5(a)(3) of this chapter.

(e) The quantity shipped is limited to an amount reasonable for the purpose of patch testing in the normal course of the practice of medicine and is used solely for such patch testing.

(f) The manufacturer or distributor maintains records of all shipments for this purpose for a period of 2 years after shipment and will make them available to the Food and Drug Administration upon request.

[43 FR 11151, Mar. 17, 1978]

Subpart D—Records and Reports

§ 433.30 Records retention.

At the option of the person having control of records required to be kept by any regulation in this part 433, photostatic or other permannnt reproductions may be substituted for such